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Clinical Laboratory Improvement Advisory Committee
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September 12, 2002

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20220

Dear Secretary Thompson:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's deep concern that rapid tests for human immunodeficiency virus (HIV) infection are being promoted for a waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) without presentation and review of data demonstrating that the CLIA waiver criteria are met. Data must be evaluated before an appropriate decision regarding waiver can be made.

As you know, CLIAC was chartered in February, 1992 to provide you and the Assistant Secretary of Health with scientific and technical advice and guidance relative to quality laboratory testing. CLIAC has, at several of its meetings, discussed in-depth the criteria used to obtain waiver under CLIA and the process for waiver review. CLIAC has also reviewed the potential public health benefits and risks of a waiver of a rapid HIV test. On September 11-12, 2002, CLIAC again considered this issue. After careful review and thoughtful discussion, the Committee's voting members unanimously requested that I share with you our concerns in this matter.

We believe that consideration of rapid HIV tests for waiver under CLIA requires a review of objective data for the following reasons:

- The results of HIV tests are of enormous consequence to the persons being tested.
- Erroneous HIV test results – both false positives and false negatives – pose a substantial risk to the persons being tested and their partners.
- Even the simplest HIV testing device requires oversight, training of personnel, quality control, proficiency testing, and quality assurance to provide accurate results.
- Waiver under CLIA provides no mechanism to assure proper oversight, personnel training, quality control, proficiency testing, and quality assurance.
- Studies performed by the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services and the Office of the Inspector General have shown that CLIA-waived tests are often incorrectly performed.
- Incorrectly performed waived tests have resulted in harm to patients.

We agree that HIV testing should be made broadly and rapidly available, and we believe this can be accomplished without waiver under CLIA. Mechanisms exist within CLIA to permit rapid HIV tests to be performed in mobile and non-traditional settings with a minimum of burden, while assuring appropriate oversight, quality control, and quality assurance.

Although we support broad dissemination of rapid HIV testing as soon as these tests are approved for market, we urge you to require careful review of objective evidence of test performance by waived testing personnel in waived settings before these tests are considered for waiver under CLIA.

We welcome the opportunity to work with you and other interested parties in this matter and thank you for your consideration.

Sincerely yours,

Toby L. Merlin, M.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee

cc:
Joseph O'Neill, M.D.
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The White House
Washington, DC 20502

Claude Allen, J.D.
Deputy Secretary
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